

Clinical Commissioning Policy Proposition: Vertebral Body Tethering (All ages)

Reference: NHS England 1750



**Prepared by NHS England Specialised Services Clinical Reference Group for
Spinal Services**

Published by NHS England, in electronic format only.

DRAFT FOR CONSULTATION

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1 Executive Summary

Equality Statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities

Plain Language Summary

About idiopathic scoliosis in growing children

Idiopathic scoliosis is a curvature of the spine without any obvious cause. When scoliosis continues to worsen in children that are still growing and who have tried bracing and other non-surgical methods of control, surgery may be considered.

About current treatments

Often, a scoliosis just needs to be monitored. If it worsens then a brace will usually be tried. If the brace does not control the scoliosis, surgery may be needed.

Currently, surgery consists of inserting metallic rods into the back of the spine that need lengthening at regular intervals to keep growth going (growing rod techniques) or a fusion to correct the spine with rods that are locked and do not move (instrumented scoliosis correction and fusion). Growing rods have to be converted to a fusion at the end of growth.

Spinal Rods work well in controlling the scoliosis and in maintaining some growth. However, they do stiffen the spine rather than leaving it flexible. They may also sacrifice some growth.

About the new treatment

Vertebral body tethering (VBT) is a new treatment that involves putting screws into the front of the spine (so the scar is on the side of the chest) which are connected by a flexible cord rather than a metal rod. The system works by compressing (squeezing) one side of the curved spine which aims to change the growth of that part of the spine and slowly improve the curve. The system can only be used in children that have enough growth left in their skeleton and are above the age of 8 years. It is not helpful for older children and teenagers or adults.

The advantage of VBT is that it should leave the spine flexible rather than stiff. Currently, it is not known if VBT preserves growth or what the long term effects of VBT are.

What we have decided

NHS England has carefully reviewed the evidence to treat idiopathic scoliosis in growing children with vertebral body tethering. We have concluded that there is not enough evidence to make the treatment available at this time.

2 Introduction

This document describes the evidence that has been considered by NHS England in formulating a proposal to not routinely commission vertebral body tethering.

For the purpose of consultation NHS England invites views on the evidence and other information that has been taken into account as described in this policy proposition.

A final decision as to whether vertebral body tethering for idiopathic scoliosis in growing children will be not routinely commissioned will be made by NHS England following a recommendation from the Clinical Priorities Advisory Group.

3 Proposed Intervention and Clinical Indication

Scoliosis refers to a curvature of the spine that can occur in any age group. In the paediatric population, progressive scoliosis can lead to other problems. In a younger child (below the age that growth of the skeleton has stopped or slowed down) a scoliosis can progress significantly due to the amount of growth remaining. This can result in a visible deformity, pain, psychological morbidity and, if severe, cardiorespiratory problems.

In the growing spine, current intervention consists of monitoring, bracing or surgery (instrumented fusion).

The size of a scoliosis curve is measured as an angle, with zero degrees being a normal straight spine. Monitoring is appropriate for curves that measure less than 20° or curves showing no progression.

Bracing is often commenced when a curve measures 20° to 40°. Bracing has evidence supporting its use with beneficial outcomes when the child is compliant.

Currently definitive scoliosis surgery consists of fusion of the spine with instrumentation. There is evidence of long term complications with more back pain compared to the general population. This may lead to further surgery.

Fusion is inappropriate in a young child as it will stunt spinal growth. As such limited fusion techniques have been utilised when the scoliosis has been shown to have

progressed or is at risk of progressing. These involve operations commonly known as “growing rod procedures” (see NHS England Clinical Commissioning Policy of Non-invasively lengthened spinal rods for scoliosis) where the implants allow the spine to grow by distracting (stretching) at regular intervals or by allowing the growing spine to slide along the implants. However these techniques are known to often require further surgery. At the end of growth, the growing rods are converted to conventional fusion techniques that stiffen the spine.

Vertebral body tethering refers to the use of implants in a subset of children with scoliosis that are still growing (skeletal immature) where the implant modifies the growth of individual spine bones in an effort to correct the curvature with time. The techniques exploit a known reaction of bone to being stretched or being compressed. This response is known as the Heuter-Volkman law and notes that bone growth increases when stretched and decreases when compressed (pressed). In scoliosis this response can be used on a curved spine if the bones still have significant growth potential. If the outside of a curve is squeezed (compressed) whilst the inside is left alone, there will be slowing down of growth on the outside of a curve with normal growth on the inside. This may then allow the curve to straighten up as growth progresses.

VBT uses screws as anchors into the front of the spine bones (vertebral bodies) on the outside of a curve with a flexible tensioned cord or tether that runs through the screws. This cord produces some immediate correction and also squeezes the bones over time to slow down growth on that side. During remaining growth, the convex (tethered) side is compressed and growth restricted whilst the concave side grows normally producing further curve correction. VBT involves anterior spinal surgery either performed thoracoscopically or through a mini-thoracotomy.

VBT could only be carried out in scoliosis centres that fulfil the criteria for deformity procedures as set out in the NHS England service specification, Complex Spinal Surgery (All Ages) D14/S/a.

<https://www.england.nhs.uk/wp-content/uploads/2013/06/d14-comp-spinal-surg.pdf>

VBT requires competence and infrastructure supporting operating on the front of the spine (anterior) either with open or endoscopic surgery (thoracoscopic). The advantage of this surgery is to maintain a flexible spine into adulthood and to allow early intervention that can limit surgery to a shorter section of the spine. It may avoid

the complications reported for current growing rod techniques and for instrumented spinal fusion. There are potential significant advantages for this group of patients. Animal studies have shown that growth modulation occurs and that fusion is avoided despite implants being placed on the spine.

Growth modulation surgical techniques have been performed in the United States of America but the published evidence is only available for small cohorts of patients and there are no long term published outcomes beyond 2 years.

The published evidence is not supportive for all groups of scoliosis patients and only exists for a subgroup of patients with idiopathic (unknown cause) scoliosis, aged 8 years or over and with specific inclusion / exclusion criteria discussed below. There has been no direct comparison with bracing or conventional techniques.

4 Definitions

Scoliosis: a curvature of the spine.

Deformity: a visible shape change of the spine.

Idiopathic: there is no known cause.

Instrumented: surgically inserting implants into the spine.

Fusion: a surgical procedure which joins together permanently two or more vertebrae.

Psychological: relating to mental health and well-being.

Morbidity: disease or disorder.

Cardiorespiratory: relating to the heart or lungs.

Bracing: applying a brace (jacket) to the body to correct a curved spine.

The Heuter-Volkman law: This relates to the fact that bone growth increases when stretched and decreases when compressed (pressed).

Vertebral body: the large chunky bones that are the front of the spine.

Anterior: the front of the spine.

Thoracotomy and mini-thoracotomy: making a cut on the side of the chest and operating through the ribs to get into the chest and operate on the spine through the chest.

Thoracoscopic or endoscopic: using smaller wounds on the side of the chest and then using a telescope through the smaller wounds to look into the chest and

complete the operation.

Growth modulation: influencing the growth of a bone.

Cohort: group.

5 Aims and Objectives

This policy proposition considered: the suitability of VBT and its long term advantages in the UK population.

The objectives were to:

- Evaluate current evidence and clinical experience.
- Identify risks and complications associated with the procedure.
- Identify the correct inclusion and exclusion criteria for the procedure.

6 Epidemiology and Needs Assessment

The prevalence of adolescent idiopathic scoliosis (AIS) is estimated at 2% to 3% of children between 10 and 16 years of age, using a definition of over 10° spine curvature. Larger curves present at a lower frequency and it is estimated that 40 degree curves make up 0.1% of the total AIS population. Although data is incomplete the estimated number of patients that would be suitable for VBT would be approximately 80 patients per year (extrapolated from British Spine Registry data).

7 Evidence Base

NHS England has concluded that there is not sufficient evidence to support a proposal for the routine commissioning of this treatment for the indication.

An evidence review found that although the biomechanical principles behind VBT are reasonably well-established from animal models, the literature at present contains only limited evidence that Vertebral Body Tethering is safe, acceptable and effective for treatment of Adolescent Idiopathic Scoliosis. This evidence is limited in that it consists entirely of clinical case reports, with no experimental or controlled studies in humans, and thus no systematic reviews or randomised controlled trials. Furthermore no evidence was found for key outcomes, including patient experience (SRS 22 / EQ-5D), pulmonary function tests, gait analysis and range of motion (thoracic and lumbar) and sitting height / T1-S1 and T1-T12 length. Complications

are reported in the literature, with the potential for overcorrection clear. There were 6 instances reported where further surgery was required.

The clinical opinion expressed in the reviewed studies is that this is a promising technique and further studies are required to demonstrate effectiveness. However, the lack of comparison in the studies reviewed means that, at present, the literature does not contain strong evidence that this technique is more effective than standard care. Further research, including experimental studies, is needed to confirm the safety, patient acceptability & effectiveness of this technique. Further studies should include outcomes relating to pulmonary function, gait analysis, range of motion and patient experience.

8 Documents That Have Informed This Policy Proposition

None.

9 Date of Review

This document will lapse upon publication by NHS England of a clinical commissioning policy for the proposed intervention that confirms whether it is routinely or non-routinely commissioned.

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